IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

HELEN FRANZMAN

Plaintiff,

v.

WYETH, INC.
C.T. Corporation System
120 South Central Avenue
Clayton, MO 63105

WYETH PHARMACEUTICALS
c/o Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

SCHWARZ PHARMA, INC.
c/o CSC Entity Services, LLC,
2711 Centerville Road
Wilmington, DE 19808

ALAVEN PHARMACEUTICALS, INC.
C.T. Corporation System
120 South Central Avenue
Clayton, MO 63105

WATSON LABORATORIES, INC.[1]
c/o CT Corporation System
818 W 7th Street
Los Angeles, CA 90017-3407

and,

FIRST DATABANK
c/o CT Corporation System
120 South Central Avenue
Clayton, MO 63105

Defendants.

Case No. 1002-CC12326
JURY DEMAND

[1] WATSON LABORATORIES, INC. was inadvertently, incorrectly named previously as WATSON PHARMACEUTICALS, INC. in the original petition. The claims made against WATSON LABORATORIES, INC. are identical to those made against WATSON PHARMACEUTICALS, INC. in the original petition, and therefore relate back to the original filing.

EXHIBIT 1

AMENDED PETITION

I. INTRODUCTION

COMES NOW Plaintiff, by and through undersigned counsel, and for her Amended Petition against Defendants alleges as follows.

1. This is a pharmaceutical tort action brought on behalf of Helen Franzman, arising out of the negligence, negligent misrepresentation and breach of warranty of the Defendants in their manufacture, promotion, distribution, sale and/or provision of incomplete, inaccurate information related to Reglan, Metoclopramide and/or Metoclopramide HCl ("Reglan/MCP"). As a result, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

II. PARTIES

2. Plaintiff Helen Franzman ("Ms. Franzman") resides in the city of Louisville, Jefferson County, Kentucky.

3. Ms. Franzman indentified *supra*, inclusive, may be referred to in this Petition as the "Plaintiff."

4. Defendant **WYETH, INC. D/B/A WYETH, LLC** is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940 and regularly conducts business in the City of St. Louis, Missouri.

5. Defendant **WYETH, INC. D/B/A WYETH, LLC** ("Wyeth") is a Delaware corporation with a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940 and regularly conducts business in the City of St. Louis, Missouri.

6. Defendant **WYETH PHARMACEUTICALS, INC**. has a principal place of

business at 500 Arcola Road, Collegeville, Pennsylvania 19426 and regularly conducts business in the City of St. Louis, Missouri.

7. Based upon information and belief, Wyeth also manufactures and distributes generic Reglan/MCP through its ownership of ESI, Lederle, Inc., ("ESI") a former subsidiary, which merged into WYETH and regularly, conducts such business in the County of St. Louis, for which it derives significant and regular income.

8. References in this Petition to Defendant "**WYETH,**" shall include collectively Defendants, **WYETH, INC. D/B/A WYETH, LLC**. and **WYETH PHARMACEUTICALS, INC**. and shall also include individually and collectively all current and/or former divisions and/or subsidiaries, **WYETH** as successor in interest to A.H. Robins, Inc., American Home Products Corporation, and ESI, Lederle, Inc.

9. **WYETH** is subject to the jurisdiction and venue of this Court.

10. Defendant **SCHWARZ PHARMA, INC.** is a Delaware corporation, with its principal place of business in 1950 Lake Park Dr. SE, Smyrna, Georgia 30080, and regularly conducts business in the City of St. Louis, Missouri.

11. Defendant **SCHWARZ PHARMA, INC.** ("Schwarz) is subject to the jurisdiction and venue of this Court.

12. **WYETH** is subject to the jurisdiction and venue of this Court.

13. Defendant **SCHWARZ PHARMA, INC.** is a Delaware corporation, with its principal place of business in 1950 Lake Park Dr. SE, Smyrna, Georgia 30080, and regularly conducts business in the City of St. Louis, Missouri.

14. Defendant **SCHWARZ PHARMA, INC.** ("Schwarz") is subject to the jurisdiction and venue of this Court.

15. Defendant **ALAVEN PHARMACEUTICAL, LLC** is a limited liability company organized under the laws of the State of Georgia, which has its principal place of business located at 2260 Northwest Parkway #A, Marietta, Georgia 30067, and regularly conducts business in the City of St. Louis, Missouri.

16. Defendant **ALAVEN PHARMACEUTICAL, LLC** ("Alaven") is subject to the jurisdiction and venue of this Court.

17. Defendant **WATSON LABORATORIES, INC.** is a corporation organized under the laws of the State of Nevada, which has its principal place of business located at 311 Bonnie Circle, Corona, CA 92880, and regularly conducts business in the City of St. Louis, Missouri.

18. Defendant **WATSON LABORATORIES, INC.** ("Watson") is subject to the jurisdiction and venue of this Court.

19. Upon information and belief, Defendant **FIRST DATABANK**, 1111 Bayhill Drive, San Bruno, California, 94066, is a Missouri corporation with its principal place of business in California. **FIRST DATABANK** regularly conducts significant business in the City of St. Louis, Missouri. **FIRST DATABANK** may be served with process through its registered agent: CT Corporation System, 120 South Central Ave., Clayton, MO 63105.

20. Defendant **FIRST DATABANK** ("FDB") is subject to the jurisdiction and venue of this Court.

21. Wyeth, Schwarz, Alaven identified *supra*, inclusive, and each of them, may be referred to in this Petition collectively as the "Brand Defendants." Brand Defendants were engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities Reglan/MCP in the State of Missouri and in interstate

commerce.

22. Watson identified *supra*, inclusive, may be referred to in this Petition as the "Generic Defendant." Generic Defendant was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities Reglan/MCP in the State of Missouri and in interstate commerce.

23. First DataBank identified *supra*, inclusive, may be referred to in this Petition as the "PEM Defendant." PEM Defendant was engaged in the business of providing patient education monographs to residents of the State of Missouri and engaged in business in the State of Missouri and in interstate commerce.

24. Wyeth, Schwarz, Alaven, Watson, and First DataBank identified *supra*, inclusive, and each of them, may be referred to in this Petition collectively as the "Defendants."

25. At all times relevant hereto, the Defendants were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment, by agency or authority.

III. VENUE AND JURISDICTION

26. This Court has jurisdiction over this matter, as an amount of damages in such sum as is fair and reasonable to compensate the Plaintiff in an amount in excess of TWENTY FIVE THOUSAND DOLLARS ($25,000).

27. The City Court of St. Louis, Missouri has original jurisdiction over this matter and this action is not subject to federal jurisdiction or removal to federal court under the provisions of 28 U.S.C. § 1332 because the claims asserted in this action relate to a tort committed in the City of St. Louis in the State of Missouri.

28. This Court has jurisdiction over the Defendants because they have offices and/or their principal place of business in Missouri, are incorporated in Missouri and/or regularly solicited and transacted business in the State of Missouri and City of St. Louis. Defendants reasonably expected that Reglan, Metoclopramide and/or Metoclopramide HCl (hereinafter referred to as "Reglan/MCP") would be prescribed, sold by pharmacies with patient education information monographs, and consumed in Missouri and the City of St. Louis.

29. At all times relevant hereto, Brand Defendants were engaged in the business of testing, developing, manufacturing, labeling, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/MCP in the City of St. Louis in the State of Missouri.

30. At all times relevant hereto, Generic Defendant was engaged in the business of developing, manufacturing, labeling, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/MCP in the City of St. Louis in the State of Missouri and in interstate commerce, for which it derived significant and regular income.

31. At all times relevant hereto, PEM Defendant was engaged in the regular business of providing patient drug information, including patient education monographs (PEMs) for branded and or generic Reglan/Metoclopramide, directly or indirectly, through third parties, as successor in interest, or other related entities, to Plaintiff and consumers in the City of St. Louis in the State of Missouri, for which it derived significant and regular income. PEM Defendant had a reasonable expectation that the information it provided would be distributed or used in the State of Missouri and the County of the United States of America, and thus has regularly and solicited and/or transacted business in the State of Missouri and the County of the United States

of America.

32. At all times relevant hereto, PEM Defendant was engaged in the regular business of providing drug information, including drug database information, clinical decision support modules, and drug monographs for branded and or generic Reglan/Metoclopramide, directly or indirectly, through third parties, as successor in interest, or other related entities, to physicians, hospitals, pharmacists and pharmacies in the City of St. Louis, Missouri, for which it derived significant and regular income.

33. This Court also has jurisdiction because several Defendants have registered agents in the State of Missouri.

IV. FACTS GIVING RISE TO PLAINTIFF'S CLAIMS

A. REGLAN/METOCLOPRAMIDE BACKGROUND

34. At all relevant times up to approximately the end of 2001, Defendant Wyeth (as the A.H. Robins Company and/or American Home Products Corporation and/or by some other name) marketed and manufactured and/or distributed a certain name brand prescription drug product known as Reglan.

35. At all relevant times between approximately the end of 2001 and up to approximately March 2008, Defendant Schwarz marketed and manufactured and/or distributed the prescription drug product known as Reglan.

36. At all relevant times after March 2008, Defendant Alaven marketed and manufactured and/or distributed the prescription drug product known as Reglan.

37. Generic Defendant Watson and other generic manufacturers began manufacturing and selling Reglan/MCP in or around 1982, and more than a dozen generic manufacturers have manufactured Reglan/MCP over the past eighteen years.

38. The generic Metoclopramide products contain the same active ingredient (i.e., drug substance) as brand name Reglan, and are equivalent to brand name Reglan products in dosage, strength, and all other therapeutically material respects, including potentially beneficial effects and potentially harmful side effects, and differ from brand name Reglan only in therapeutically non-relevant respects such as color, shape, inactive ingredients, and source of manufacture.

39. The term "Reglan" is the brand name for a drug known generically as Metoclopramide, or Metoclopramide hydrochloride or Metoclopramide HCl, terms, which also refer to the drug substance that is the sole active ingredient in Reglan.

40. Reglan/MCP is a prescription medication classified as a GI stimulant, antiemetic and Dopaminergic blocking agent. It is indicated for short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

41. The active ingredient, Metoclopramide and Metoclopramide HCl, is a dopamine receptor-blocking drug. As Metoclopramide blocks dopamine transfer in the brain, it causes the brain to react and to produce more dopamine receptors so that areas controlling movement become hypersensitive to dopamine, in effect to overreact.

42. Reglan/MCP is indicated for treatment use of no greater than twelve weeks; however, Defendants represented that Reglan/MCP was safe for use to treat nausea and or esophageal reflux for durations that exceeded twelve weeks.

43. Patients who use Reglan/MCP for long periods (exceeding twelve weeks) are at a significant and unreasonably dangerous increased risk of developing a severe and permanent neurological movement disorder, known as Tardive Dyskinesia, Dystonia and/or Tremors.

44. Other serious side effects that may be caused by ingesting Reglan/MCP for longer

periods of time include, but are not limited to, central nervous system disorders, depression with suicidal ideation, Akathisia, Tardive Dyskinesia, Tardive Dystonia, Tremors, visual disturbances and interference with drug metabolism.

45. Patients who use Reglan/MCP for long periods of time (greater than twelve weeks) who are not able to effectively metabolize it are at a greater risk of developing these serious and permanent injuries.

46. Tardive Dyskinesia, Dystonia and Tremors are serious side effects associated with the ingestion of Reglan/MCP and are debilitating neurological disorders that often result in involuntary and uncontrollable movements of the head, neck, face, arms, legs and/or trunk, as well as, involuntary facial grimacing and tongue movements, including tongue thrusting, tongue chewing and/or other involuntary movements.

47. There is no known cure for Tardive Dyskinesia, Dystonia, Stereotypy, Tremors or Akathisia.

B. PLAINTIFF DEVELOPED TARDIVE DYSKINESIA AND OROLINGUAL FACIAL BUCCAL STEREOTYPE AS A RESULT OF INGESTING REGLAN/METOCLOPRAMIDE

48. Plaintiff brings this action for the purpose of recovering damages for the personal injuries and emotional distress she has suffered as a result of being prescribed and ingesting Reglan/MCP.

49. In or around March 2002 through October 2005, Ms. Franzman ingested 30-40mg of Reglan/MCP per day to treat gastroparesis, as prescribed by her physician. During that period of time, Ms. Franzman ingested high doses of Reglan/MCP for three and a half years.

50. The Reglan/MCP Ms. Franzman ingested was manufactured by the Generic Defendant, Watson Laboratories, Inc.

51. Upon information and belief, the PEM Defendant, FDB, authored the PEM used by Plaintiff's Pharmacy, Ireland Army Community Hospital Pharmacy (hereinafter "Army Pharmacy" or "Plaintiff's Pharmacy"), where Ms. Franzman filled her Reglan/MCP prescriptions.

52. During the time that Ms. Franzman used Reglan/MCP and continuing through the present, she experienced abnormal, involuntary movements of her mouth, tongue, jaw, grinding and wearing of teeth, and tongue biting.

53. Ms. Franzman sought treatment from her primary care physician, Dr. Sharma, on or about October 2005. Ms. Franzman presented with repetitive and involuntary movements affecting her jaw, mouth and tongue.

54. On or about October 2005, pursuant to the direction of her physicians, Ms. Franzman discontinued her Reglan/MCP use.

55. Ms. Franzman continued to seek treatment for her symptoms with movement disorder specialist, Dr. Walter Olson, in March 2006. Dr. Olsen diagnosed her with Tardive Dyskinesia and, more specifically, diagnosed her with Orolingual Facial Buccal Stereotypy secondary to Reglan/MCP.

56. Ms. Franzman has sought, and continues to seek, treatment for her Reglan/MCP induced injuries from a movement disorder specialist.

57. A stereotypy is a repetitive or ritualistic movement or posture found in patients with TD. Orolingual Facial Buccal Stereotypy is involuntary, repeated, rhythmic purposeless movements of the muscles of the lower face, lips, and tongue.

58. Tardive Dyskinesia ("TD"), one of the serious side effects associated with the ingestion of Reglan/MCP, is characterized by involuntary, repetitive movements of the

extremities, or lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is no known treatment for TD. Significant psychosocial morbidity, decreased quality of life, and even mortality have been attributed to TD.

59. Ms. Franzman's TD, and specifically her Orolingual Facial Buccal Stereotypy, have resulted in her experiencing persistent, involuntary movements of her eyes, mouth, jaw and tongue, embarrassment and difficulty with essential activities of daily living including eating, swallowing, and speaking. In addition her jaw movements have resulted in her biting her tongue and cracking six of her teeth.

60. Due to her ingestion of Reglan/MCP, Ms. Franzman is forced to take Naltrexone to treat her Reglan/MCP induced injuries. Being forced to take this medication has put Ms. Franzman at risk for developing another serious condition and/or disorder, such as hepatocellular injury. In addition to the risk of another disorder, Naltrexone, an opiod antagonist, blocks the efficacy of Ms. Franzman's pain relievers, which she had been taking for back pain, leaving her in additional pain.

61. Upon information and belief, Ms. Franzman's TD, and specifically Orolingual Facial Buccal Stereotypy, has been linked to her use of Reglan/MCP.

62. At no time, prior to her diagnosis of Reglan/MCP induced TD was Ms. Franzman knowledgeable or informed of the dangerous side effects associated with prolonged exposure to Reglan/MCP.

63. At no time prior to mid-2009, was Ms. Franzman aware that she was wronged by one or more of the Defendants, nor which Defendant(s) committed the wrongs that caused her TD and Orolingual Facial Buccal Stereotypy.

64. Upon information and belief, Ms. Franzman's Tardive Dyskinesia, a severe and often permanent, painful, disfiguring and debilitating neurological movement disorder, caused by the ingestion of Reglan/MCP, and related Orolingual Facial Buccal Stereotypy, are likely permanent.

65. Moreover, at present, there is no cure for TD, nor is there a cure for Orolingual Facial Buccal Stereotypy, from which she suffers.

66. Upon information and belief, in prescribing the Reglan/MCP to the Plaintiff long-term and/or at high doses, their prescribing doctors relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

67. Plaintiff's physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR and package insert.

68. Plaintiff ingested the Reglan/MCP as prescribed. Plaintiff also used the pharmaceutical drugs Reglan/MCP without substantial change in the condition of the drugs between the time of design and manufacture of the drugs and the time the drugs were used as directed.

69. Prior to ingesting Reglan/MCP, Plaintiff never experienced the abnormal, involuntary movements, TD or any form of Orolingual Facial Buccal stereotypy, which she developed only after her ingestion of Reglan/MCP.

70. Plaintiff was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated

in the PDR, RLD, by the NDA Holders, Brand Defendants and Generic Defendant and/or in the Patient Education Monograph authored by the PEM Defendant, FDB.

71. During the time of her ingestion of Reglan/MCP, Plaintiff remained at all times unaware of the potential risks, side effects and/or relationship between the continued ingestion of Reglan/MCP as prescribed and the physical symptoms that she was developing.

72. Had Plaintiff known of the risks associated with long-term ingestion of Reglan/MCP she would not have taken the drug.

73. Plaintiff's ingestion of Reglan/MCP, as prescribed, resulted in unnecessary and unreasonably dangerous overexposure to the drug. Use of Reglan/MCP caused Plaintiff to suffer serious, permanent and disabling injuries including but not limited to injuries of or associated with the central nervous and extrapyramidal motor systems. Because of the injuries Plaintiff suffered from the use of Reglan/MCP, Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages.

74. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Reglan/MCP and the ingestion of Reglan/MCP to the medical community, physicians, Plaintiff's physicians, Plaintiff and other foreseeable users of the drug.

75. The United States Food and Drug Administration did not approve Reglan/MCP for long-term use or for use longer than twelve weeks.

76. Because of the misleading information that the Defendants provided to physicians, consumers and the United States Food and Drug Administration (hereinafter referred

to as "FDA") about the true risks associated with the use of Reglan/MCP and because of the failure of the Defendants and each of them to adequately inform physicians generally, including Plaintiff's physicians and pharmacists, about the true risks associated with the use of Reglan/MCP, at all times relevant to this lawsuit, while Plaintiff was taking Reglan/MCP, her physicians never informed her of the true risks of the involuntary movement disorders associated with Reglan/MCP or that Reglan/MCP was only approved for short-term use (up to twelve weeks).

77. At all times material hereto, Defendants knew or should have known of the serious side effects caused by Reglan/MCP including, but not limited to, central nervous system disorders, depression with suicidal ideation, Akathisia, Tardive Dyskinesia, Tardive Dystonia, Stereotypy, Tremors, visual disturbances and interference with drug metabolism.

78. As a result of the misrepresentations, breach of express and implied warranties and/or negligence of the Defendants, Plaintiff was prescribed excessive amounts of Reglan/MCP, which caused her to suffer serious, and permanent injuries as described above.

79. As a result of the foregoing acts and omissions, Plaintiff requires and will require health care and services, and has incurred and will continue to incur medical and related expenses. Plaintiff has suffered and will continue to suffer indirect costs, including diminished quality of life, and direct medical costs for follow-up care, including hospitalizations, treatment and other medical care.

80. Recognizing the inadequate nature of the Manufacturing Defendants' label and warnings, in February 2009 the United States Food and Drug Administration (hereinafter referred to as "FDA") issued an advisory requiring the addition of a **Boxed Warning** for Reglan/MCP. This new warning, appearing at the top of the label, states that "Chronic treatment

with Metoclopramide can cause Tardive Dyskinesia, a serious movement disorder that is often irreversible . . . ." Additionally, the new Boxed Warning now tells physicians and patients that "Prolonged treatment (greater than twelve weeks) with Metoclopramide should be avoided in all but rare cases . . . ."

81. Finally, the FDA is now requiring that Manufacturing Defendants implement a Risk Evaluation and Mitigation Strategy because the FDA has determined that the use of Reglan/MCP "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide." This Medication Guide, setting out all the risks of the drug and to be given to all users "is necessary for the patients' safe use of Reglan (Metoclopramide) . . . ." Unfortunately, upon information and belief, neither this Boxed Warning nor the Medication Guide was available to Ms. Franzman when she ingested Reglan/MCP.

82. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential effects of exposure to and long-term ingestion of Reglan/MCP to the medical community, Plaintiff, and other foreseeable users of the drug.

83. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain, suffering, diminished quality of life, psychological injury, and/or other injuries and damages due to her prescription and ingestion of Reglan/MCP.

C. DEFENDANTS' WRONGFUL CONDUCT

84. This case involves Defendants' failure to warn physicians and patients of information within their knowledge or possession which indicated that Reglan/MCP, when taken

for long periods of time, caused serious, permanent and debilitating side effects, including the injuries suffered by Plaintiff.

85. Defendants jointly and severally marketed, manufactured and distributed Reglan/MCP and/or encouraged the long-term use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

86. Wyeth is the successor-in-interest to A.H. Robins Company, Inc., which first obtained approval by the FDA to distribute Metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA)[2] schema in 1983.

87. Defendant Wyeth's predecessor in interest, A.H. Robins Company, Inc. expressly warranted to physicians that Reglan/MCP is safe for long-term use.

88. A.H. Robins knew that its warranties regarding safety for long-term use would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their communities and that eventually physicians would come to rely on A.H. Robins' express warranties about the safety of long-term use of Reglan/MCP.

89. A.H. Robins' express warranties about the safety of Reglan/MCP for long-term use were false and intentionally and negligently misleading.

90. As successor-in-interest to A.H. Robins Company, Inc., Wyeth is legally responsible for the conduct, fraudulent and negligent acts, intentional and willful omissions, and misleading representations and warranties made my A.H. Robins Company, Inc. concerning the safety and adequacy of Reglan/MCP, and all liabilities stemming there from.

91. Wyeth manufactured, marketed and distributed Reglan, Metoclopramide, and/or Metoclopramide HCl through its Wyeth-Ayerst Laboratories Division in St. David's,

[2] Upon information and belief, Wyeth is the holder of multiple NDAs for Reglan, metoclopramide and metoclopramide HCl.

Pennsylvania and through its ownership of "ESI."[3]

92. Wyeth knew that it must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results involving animal studies, clinical studies, and the drug's bioavailability.

93. Wyeth knew that the data and information would be relied upon by the medical community, physicians, Plaintiff, and other foreseeable users of Reglan/MCP once the NDA was approved and Wyeth was listed and the Reference Listed Drug Company for the drug.

94. Wyeth intentionally and negligently disseminated misleading information to physicians across the county, through the PDR and otherwise, about the risks of long-term ingestion of Reglan/MCP and the increased risk of extrapyramidal side effects, including Tardive Dyskinesia, Dystonia, Orolingual Facial Buccal Stereotypy, Akathisia, and Tremors.

95. Defendant Schwarz purchased from Wyeth the rights and liabilities associated with Reglan/MCP, the terms of which, upon information and belief, obligated Schwarz to be responsible for claims related to the ingestion or use of Reglan/MCP in or around 2001.

96. Defendant Schwarz entered into an indemnification agreement with Wyeth over the purchase of the innovator, Wyeth's, Reglan, which included disclosure of clinical studies on Reglan/MCP that were not publicly available.[4]

97. Because Defendant Schwarz acquired Defendant Wyeth's Reglan/MCP assets and liabilities while Wyeth was involved in ongoing litigation regarding Reglan/MCP, and nevertheless agreed to indemnify Wyeth against all claims related to the ingestion of the drug,

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[3] Upon information and belief, ESI was a former subsidiary which merged into Wyeth on or about December 15, 1998.

[4] Plaintiff does not have information regarding the maximum amount of liability under the Defendants' indemnification agreement.

Schwarz knew or should have known that the NDA label for Reglan/MCP (Wyeth's label) misrepresented the safety of the drug, withheld warnings of the known side effects of the drug, and knew or should have known of the safety issues surrounding it.

98. Under the FDA schema, Wyeth was and is the Reference Listed Drug Company (RLD), under a specific NDA, for Reglan/MCP.

99. Under the FDA schema, Defendant Schwarz was and remains the RLD and/or NDA Holder for Reglan/MCP.

100. At all times material hereto, Defendants Wyeth and Schwarz, as the NDA Holder and/or RLD companies, were aware of the serious side effects caused by Reglan/MCP including, but not limited to, central nervous system disorders, depression with suicidal ideation, Akathisia, Tardive Dyskinesia, Tardive Dystonia, Tremors, Orolingual Facial Buccal Stereotypy, Akathisia, visual disturbances and interference with drug metabolism.

101. Defendant Alaven also manufactures, markets, and distributes Reglan, Metoclopramide, and/or Metoclopramide HCl through its facility in Marietta, Georgia.

102. Defendants Wyeth, Schwarz and Alaven have a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report any data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

103. Defendants Wyeth, Schwarz and Alaven represented that Reglan/MCP was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose, that there were safer alternatives, and that the drug was dangerous to the health and body of users, including the health and body of the Plaintiff, Ms. Franzman.

104. Defendants Wyeth, Schwarz and Alaven represented that Reglan/MCP caused

minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented.

105. Defendants Wyeth, Schwarz and Alaven had actual knowledge, through their own studies and studies by independent investigators, that physicians frequently prescribed Reglan/MCP for long-term use, which was not safe for their patients.

106. Defendants Wyeth, Schwarz and Alaven had actual knowledge, through their own studies and studies by independent investigators that nearly one-third (1/3) of all patients who used Reglan/MCP received it on physician's prescriptions for twelve months or longer, rather than twelve weeks or less.

107. Defendants Wyeth, Schwarz and Alaven also had actual knowledge, through research by independent investigators, that the risk of Tardive Dyskinesia, Dystonia and other extrapyramidal side effects of Reglan/MCP in patients who received the drug for twelve weeks or longer are as high as 27% to 29% and consequently, the risk is exorbitantly greater than suggested in the package inserts and the PDR.

108. Defendants Wyeth, Schwarz and Alaven knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/MCP are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

109. Defendants Wyeth, Schwarz and Alaven had actual knowledge of facts, which demonstrated that representations in the Reglan/MCP package insert, the PDR and literature they distributed to physicians were false and misleading.

110. Defendants Wyeth, Schwarz and Alaven failed to correct their package insert and/or disclose that knowledge to the medical community, the Plaintiff, and other foreseeable

users.

111. It is the public policy of the United States and of the State of Missouri, as reflected in the Hatch-Waxman Act, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

112. Defendants Wyeth, Schwarz and Alaven, as prescription drug manufacturers and/or distributors, knew that so-called "drug product selection laws," enacted in every state, including the State of Missouri, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limitations, with a generic drug product that is therapeutically equivalent to the name brand drug product.

113. Defendants Wyeth, Schwarz and Alaven had actual and/or constructive knowledge that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product, which gives the impression to prescribers and consumers that the information contained in the package inserts accompanying their own generic prescription drugs is accurate and not misleading.

114. Defendants Wyeth, Schwarz and Alaven had actual and/or constructive knowledge that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

115. Defendants Wyeth, Schwarz and Alaven had actual and/or constructive knowledge that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and that physicians rely upon that information in their decisions concerning the prescribing of those products for their patients.

116. Defendants Wyeth, Schwarz and Alaven had actual and/or constructive knowledge that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Metoclopramide.

117. Generic Defendants submitted Abbreviated New Drug Applications ("ANDA") to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Metoclopramide and/or Metoclopramide HCl.

118. Under the ANDA process, the Code of Federal Regulations required generic manufacturers, such as Watson, to submit labels for Metoclopramide and/or Metoclopramide HCl initially identical in all material aspects to the reference listed drug label.

119. Under the Code of Federal Regulations, Generic Defendant has a duty to ensure its Reglan/MCP warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/MCP.

120. Under the Code of Federal Regulations, if the Generic Defendant discovers information in the course of the fulfillment of its duties as outlined above, it must report that information to the FDA, and to the medical community, the Plaintiff, and other foreseeable users of Reglan/MCP to ensure that its warnings are continually accurate and adequate.

121. The Generic Defendant who manufactured the Reglan/MCP ingested by Ms. Franzman, Watson, failed to investigate the accuracy of its Metoclopramide and/or Metoclopramide HCl drug labels.

122. Generic Defendant Watson failed to review the medical and scientific literature

for the Metoclopramide drug and/or Metoclopramide HCl drug.

123. Generic Defendant Watson failed to fulfill its duties of pharmacovigilance before and after approval of its ANDAs for the Metoclopramide drug and/or Metoclopramide HCl drug.

124. Generic Defendant Watson relied upon the name brand manufacturer and the referenced listed drug companies to review the aforementioned medical and scientific literature for Reglan/MCP.

125. Under the FDA schema, if the FDA approves a label change as requested by an ANDA holder, the NDA holder (also referred to as the RLD Company) must also amend its label and vice versa.

126. Generic Defendant Watson failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Metoclopramide and/or Metoclopramide HCl.

127. Brand Defendants and Generic Defendant disseminated to physicians, through package inserts, the publication of the PDR, patient education monographs, and otherwise, information concerning the properties and effects of Reglan/MCP, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients, including Ms. Franzman.

128. Ireland Army Community Hospital Pharmacy ("Plaintiff's Pharmacy" or "Army Pharmacy") sold Reglan/MCP to the Plaintiff, and other individuals, in the regular course of business at Army Pharmacy.

129. Pursuant to regulations, pharmacies, like Army Pharmacy, provide written information (The Patient Education Monograph or "PEM") to its consumers or customers with each prescription medicine.

130. The PEM Defendant, FDB, contracted with Plaintiff's Pharmacy to provide patient drug information in various forms and specifically in written form available to Army Pharmacy's customers at the time a filled prescription is picked-up. This information is usually stapled to the outside of prescription bag at the time of purchase and is the last drug safety and risk information provided to the Plaintiff prior to her ingesting the drug.

131. Plaintiff relied upon the inadequate Reglan/MCP risk information provided to her by her pharmacy when she was ingesting Reglan/MCP.

132. Plaintiff read and relied upon FDB's misstatements regarding the true risks associated with Reglan/MCP, as set forth in its PEM provided to Ms. Franzman by Army Pharmacy with her prescriptions.

133. The FDA does not regulate the PEM Defendant, FDB, because of assurances by industry in the early 1980s through the mid-1990s when the FDA sought to regulate them, that PEM Defendant and other PEM authors would "self-regulate" their own conduct as to consumer medical information. As part of the assurances by industry, FDB and other PEM authors, a Steering Committee was created, consisting of healthcare professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and others. This committee developed a report titled Action Plan for the Provision of Useful Prescription Medicine Information (the "Keystone Guidelines" or "Action Plan"). [5]

134. The PEM Defendant assumed a duty to comply with the Keystone Guidelines.

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[5] *See* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ReportsBudgets/UCM163793.pdf. The Keystone Guidelines apply to both Pharmacies and PEM authors and were to delineate the criteria to evaluate whether a particular piece of written medication information was "useful" for consumers. *See id.* The purpose of the industry Guidelines was to help improve the quality and availability of useful information by voluntary standards rather than regulatory actions by FDA. *See id.* The Guidelines sought to encourage health care providers, health care professionals' associations, consumer organizations, PEM authors and other interested parties to voluntarily adopt a long-range strategy for improving availability of useful consumer-oriented information. *See id.*

135. In accordance with the Keystone Guidelines, the PEM Defendant has a duty to ensure that the PEMs and drug information provided to pharmacies, its patients, the same ones provided to the Plaintiff, are:

- scientifically accurate;
- unbiased in content and tone;
- sufficiently specific and comprehensive;
- presented in an understandable and legible format that is readily comprehensible to consumers;
- timely and up-to-date;
- useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoids harm.[6]

136. For the past two decades, studies have found, and PEM Defendant has been, or should have been aware, that the frequency of Tardive Dyskinesia among patients treated with Reglan/MCP is higher that one in four (1 in 4), or otherwise stated, between 27-29% among patients treated with Reglan/MCP.[7] In addition, Reglan/MCP has never been approved for use longer than four to twelve weeks, nevertheless, with full (actual and/or constructive) knowledge of PEM Defendant FDB, physicians routinely prescribed Reglan/MCP for longer than twelve weeks, and consumers, like Plaintiff, ingested Reglan/MCP for a period longer than the approved duration of twelve weeks.[8]

137. On February 26, 2009, the FDA was forced to act and required that a Boxed Warning be added to Reglan/MCP labeling.[9] The new manufacturer Boxed Warning and

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[6] *See id.* at pp. 16-20.
[7] *See e.g.* L. Ganzini et al., *The Prevalence of Metoclopramide-Induced Tardive Dyskinesia and Acute Extrapyramidal Movement Disorders*, 153 Arch. Internal Med. 1469 (1993).
[8] R. Stewart, et al, "Metoclopramide: An Analysis of Inappropriate Long-Term Use in the Elderly," *Annals of Pharmacotherapy* 26:977, 978 (1992). Plaintiff will provide the Court copies of all studies if interested.
[9] *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149533.htm.

labeling[10] states "**WARNING TARDIVE DYSKINESIA** Treatment with Metoclopramide can cause Tardive Dyskinesia, a serious movement disorder that is often irreversible...." and informs that "[t]he risk of developing Tardive Dyskinesia increases with duration of treatment and total cumulative dose." The label now cautions that "[t]reatment with Metoclopramide for longer than twelve weeks should be avoided in all but rare cases where the therapeutic benefit is thought to outweigh the risk of developing Tardive Dyskinesia." None of this information was contained in the PEM(s) provided to Ms. Franzman by her pharmacy and authored by the PEM Defendant.

138. The PEM Defendant failed to comply with its obligations set forth in the Keystone Guidelines, and the duties that it undertook under common law and the *Restatement of Torts*, when it failed to provide scientifically accurate, comprehensive, timely useful, and up-to-date, information to the Plaintiff regarding the risks associated with Reglan/MCP use, including, but not limited to, the one in four (1 in 4) to one in five (1 in 5) chance of developing an involuntary movement disorder with use of Reglan/MCP exceeding twelve weeks.

139. The PEM Defendant failed to disclose in its drug database information, clinical decision support modules, drug monographs, PEMs, and/or other literature, material safety information regarding the serious and permanent side effects caused by taking Reglan/MCP for long periods of time (over twelve weeks).

140. The PEM Defendant failed to disclose in its drug database information, clinical decision support modules, drug monographs, PEMs, and/or other literature, material safety information regarding the increased risks associated with Reglan/MCP for diabetics.

141. The PEM Defendant failed to disclose in its drug database information, clinical decision support modules, drug monographs, PEMs, and or other literature, material safety information regarding the fact that Reglan/MCP had not been approved by the FDA for usage in

[10] Reglan Sept. 2009 Label at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/017854s052lbl.pdf.

the pediatric population or for breastfeeding mothers.

142. The PEM Defendant undertook, had, and failed in its duty to provide truthful, accurate, appropriate and complete information and warnings in the written Reglan, Metoclopramide and/or Metoclopramide HCl PEMs, patient drug information forms, counseling, warnings, or literature, that PEM Defendant FDB created, wrote, edited, provided and made available to the Army Pharmacy to be distributed to pharmacy customers, including Ms. Franzman.

143. The PEM Defendant undertook, had, and failed in its duty to provide truthful, accurate, appropriate and complete information and warnings in the written Reglan, Metoclopramide and/or Metoclopramide HCl drug database information, clinical decision support modules, drug monographs, forms, counseling, warnings, or literature, that it created, wrote, edited, provided and made available to physicians, hospitals, pharmacists, and pharmacies, including, upon information and belief, Plaintiff's pharmacists and physicians.

144. The PEM Defendant owed a duty in all of its several undertakings, including the dissemination of information concerning Reglan/MCP, to exercise reasonable care to ensure that Plaintiff was provided accurate information about risks and benefits.

145. The PEM Defendant had actual and/or constructive knowledge specifically, that pharmacists, hospitals, physicians and consumers, including the Plaintiff and, upon information and belief, her pharmacists and physicians, would rely upon the information disseminated to them by the PEM Defendant in its drug database information, clinical decision support modules, drug monographs, patient education monograph and/or other literature for Reglan/MCP, and that many physicians, in accordance with the drug database information and drug monographs provided by PEM Defendant, would likely prescribe, and many patients, in accordance with its

prescription and patient education monograph, would be likely to ingest Reglan/MCP, without knowledge of the true risks associated with the drug.

146. The PEM Defendant knew, or should have known through the exercise of reasonable care, that the drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature for Reglan/MCP substantially understated the prevalence of acute and long-term side effects of ingesting the drug.

147. The PEM Defendant failed to review adverse drug event information and revise its drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature when information was discovered bearing upon the adequacy and accuracy of its drug database information, drug monographs, PEM warnings, efficacy, or safety information, including the risks and/or prevalence of side effects caused by Reglan/MCP.

148. The PEM Defendant failed to monitor all relevant scientific literature related to Reglan/MCP and revise its drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature when information was discovered bearing upon the adequacy and accuracy of its drug database information, drug monographs, PEM warnings, efficacy, or safety information, including the risks and/or prevalence of side effects caused by Reglan/MCP.

149. The PEM Defendant failed in its drug database information, clinical decision support modules, drug monographs, PEMs and or other literature, to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy or safety of Reglan/MCP.

150. The PEM Defendant failed to use reasonable care to modify its drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature

to adequately warn patients and physicians about the true risks of both short-term and long-term use, even after several studies established that its drug database information, PEMs and/or other literature provided inadequate warnings, efficacy and safety information, including the risks and/or prevalence of side effects caused by Reglan/MCP.

151. The PEM Defendant recklessly and deceptively concealed in its drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature, the fact that Reglan/MCP is a neuroleptic agent and dopamine antagonist, which can be expected to lead to Tardive Dyskinesia, Dystonia and other extrapyramidal side effects with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs and that epidemiological studies have consistently confirmed this expectation.

152. The PEM Defendant also recklessly and deceptively concealed in its drug database information, clinical decision support modules, drug monographs, PEMs and/or other literature, the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/MCP for longer than twelve weeks is unlikely to be reasonably safe.

153. Pursuant to Section 538.225 of the Missouri Revised Statutes, attached hereto as **Exhibits "A"** is a copy of the Affidavit of Plaintiff's Attorney Certifying the Merits of the Case as to the Defendant, First Data Bank, which attests that there is reasonable cause for filing the instant action against the PEM Defendant and that Plaintiff's claims against First Data Bank are meritorious.

154. Defendants knew, or should have known through the exercise of reasonable care, that the PDR, package insert, information publically available and PEMs for Reglan/MCP substantially understated the prevalence of acute and long-term side effects of ingesting the drug.

155. Defendants failed to use reasonable care to modify the PDR, package insert, information publically available and PEMs to adequately warn patients and physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

156. Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/MCP, to exercise reasonable care to ensure that they provided accurate information about risks and benefits.

157. Defendants failed to conduct and report post market safety surveillance on Reglan/MCP.

158. Defendants failed to review all adverse drug event information[11] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/MCP.

159. Defendants failed to monitor all relevant scientific literature related to Reglan/MCP.

160. Defendants failed to conduct appropriate safety and efficacy studies in a timely manner to support marketed risks and benefits of Reglan/MCP.

161. Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/MCP for long periods of time.

162. Defendants failed to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Reglan/MCP.

163. Defendants knowingly concealed from patients and physicians material facts

[11] Defendants are required to review all adverse drug experience information obtained or otherwise received . . . from any source...including derived from postmarketing clinical investigations, postmarketing epidemiological/ surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R. § 317.80(b).

bearing on the interpretation of package insert disclosures and PEMs, that exposure to Reglan/MCP can lead to Tardive Dyskinesia, Dystonia, Tremors and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than twelve weeks "cannot be recommended."

164. Defendants concealed the fact that earlier false information disseminated by A.H. Robins Company and/or Wyeth representing long-term Reglan/MCP therapy to be reasonably safe, was unscientific and false.

165. Defendants concealed the fact that Reglan/MCP is a neuroleptic agent and dopamine antagonist, which can be expected to lead to Tardive Dyskinesia, Dystonia, Tremors and other extrapyramidal side effects with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs and that epidemiological studies have consistently confirmed this expectation.

166. Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/MCP for longer than twelve weeks is unlikely to be reasonably safe.

167. Some, or all of the Defendants, as a result of their participation as defendants in previous litigation concerning Reglan/MCP products received clear notice of Wyeth's suppression of important safety information concerning Reglan/MCP, yet despite this notice chose to ignore the information and join consciously in the suppression.

168. As a result of all of the Defendants wrongful conduct, Ms. Franzman has suffered and continues to suffer, significant, permanent injuries.

COUNT I

NEGLIGENCE, NEGLIGENT MISREPRESENTATION AND NEGLIGENT SUPPLY OF INFORMATION FOR THE GUIDANCE OF OTHERS

PLAINTIFF V. WYETH, SCHWARZ AND ALAVEN

(BRAND DEFENDANTS)

169. Plaintiff incorporates by reference all of the above paragraphs.

170. At all times material hereto, Defendants Wyeth, Schwarz and Alaven ("Brand Defendants") were engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest or other related entities the brand drug Reglan.

171. Defendant Wyeth developed and branded the pharmaceutical drug Reglan.

172. Defendant Wyeth is the successor in interest to A.H. Robins Company, Inc., which first obtained approval by the FDA to distribute Metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA)[12] schema in 1983.

173. Defendant, Wyeth manufactured, marketed and distributed Reglan/Metoclopramide and/or Metoclopramide HCl. [13]

174. Based upon information and belief, Defendant Schwarz purchased from Defendant Wyeth the rights and liabilities associated with Reglan/MCP and the terms of which, obligated Schwarz to accept responsibility for claims related to the ingestion or use of Reglan/MCP.

175. Based upon information and belief Defendant Schwarz entered into an

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[12] Upon information and belief, Wyeth is the holder of multiple NDAs for Reglan, metoclopramide and metoclopramide HCl.

[13] Upon information and belief, ESI Lederle was a former subsidiary, which merged into Wyeth on or about December 15, 1998.

indemnification agreement with Wyeth over the purchase of the innovator, Wyeth's drug Reglan, which included disclosure of clinical studies on Reglan/MCP that were not publicly available.

176. Under the FDA schema, Defendant Schwarz was the RLD and/or NDA holder for Reglan/MCP for a period time.

177. In or around 2008, Defendant Schwarz ceased to be the RLD holder for Reglan/MCP and Defendant Alaven became the RLD and/or NDA holder. Based upon information and belief Defendant Alaven also maintained rights and liabilities associated with Reglan/MCP making it responsible for claims related to the ingestion or use of Reglan/MCP.

178. Based upon information Defendant Alaven had in its possession, disclosure of clinical studies on Reglan/MCP that were not publicly available.

179. At all times material hereto, Defendant Wyeth knew that it must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results involving animal studies, clinical studies and the drug's bioavailability.

180. At all times material hereto, Defendant Wyeth knew that the data and information would be relied upon by the medical community, physicians, the Plaintiff, and other foreseeable users of Reglan/MCP once the NDA was approved and Wyeth was listed as the Reference Listed Drug Company ("RLD") for the drug.

181. At all times material hereto, Brand Defendants, as the NDA Holder and/or RLD companies were aware of the serious side effects caused by the long-term ingestion of Reglan/MCP including but not limited to, central nervous system disorders, depression with suicidal ideation, Akathisia, Tardive Dyskinesia, Tardive Dystonia, Stereotypy, Tremors, visual disturbances and interference with drug metabolism.

182. It is further believed that Defendant Schwarz acquired Defendant Wyeth's Reglan/MCP assets and liabilities while Wyeth was involved in ongoing litigation regarding Reglan/MCP and as such agreed to indemnify Wyeth against all claims related to the ingestion of the drug. Schwarz knew or should have known that the NDA label for Reglan/MCP (Wyeth's label) misrepresented the safety of the drug, withheld warnings of the known side effects of the drug and knew or should have known of the safety issues involved.

183. Brand Defendants represented that Reglan/MCP was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of the user of said drug, including the health and body of Ms. Franzman.

184. Brand Defendants represented that Reglan/MCP caused minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented. As a direct result, Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Stereotypy, Tremors and Akathisia.

185. On or before the time Plaintiff was first prescribed Reglan/MCP, Brand Defendants had actual knowledge or should have known through the exercise of reasonable care through their own studies and/or studies by independent investigators, that physicians frequently prescribed Reglan/MCP for long-term use that was not safe for patients.

186. On or before the time Plaintiff was first prescribed Reglan/MCP, Brand Defendants through their own studies and/or studies by independent investigators, knew, or through the exercise of reasonable care should have known that nearly one-third (1/3) of all

patients who used Reglan/MCP received it on their physician's prescriptions for twelve months or longer, rather than twelve weeks or less.

187. On or before the time Plaintiff was first prescribed Reglan/MCP, Brand Defendants had actual knowledge or should have known through the exercise of reasonable care through their own studies and/or studies by independent investigators, that the risk of Tardive Dyskinesia, Dystonia and other extrapyramidal side effects (EPS) of Reglan/MCP in patients who receive the drug for twelve weeks or longer is exorbitantly greater than disclosed in package inserts and the PDR.

188. On or before the time Plaintiff was first prescribed Reglan/MCP, Brand Defendants knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/MCP are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

189. Despite information as to the significant risks and side effects associated with long-term (greater than twelve weeks) Reglan/MCP ingestion, Brand Defendants failed to correct the information published in the PDR, their package inserts and other materials and/or disclose the knowledge to the medical community, the Plaintiff, and other foreseeable users. As a direct result, Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia.

190. Brand Defendants, in the course of their business of manufacturing Reglan/MCP for which they each had pecuniary interests, supplied false information in the PDR and Reglan/MCP package inserts for the guidance of physicians, generic manufacturers of

Reglan/MCP, and/or ultimately, the Plaintiff, and consumers of brand and generic Reglan/MCP products.

191. Brand Defendants knew that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product, and that this would give the impression that the information contained in the package inserts accompanying their own generic prescription drugs is accurate and not misleading.

192. Brand Defendants knew that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

193. Brand Defendants knew that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR, package insert or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

194. Brand Defendants knew that physicians would rely upon the information disseminated to them by the name brand manufacturers, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan/MCP, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan/MCP that contained a generic patient education monograph with the same language as in the Brand name Defendants' patient education monograph.

195. Generic manufacturers, at times physicians, and ultimately the Plaintiff, justifiably relied upon the false information supplied by Brand Defendants in their Reglan/MCP package inserts and the PDR as described below.

196. Brand Defendants were aware that under the FDA schema, if the FDA approves a

label change as requested by an ANDA holder, the NDA holder (also referred to as the RLD Company) must also amend its label and vice versa.

197. Brand Defendants knew that the package insert for Reglan/MCP substantially understated the prevalence of acute and long-term side effects of ingesting the drug.

198. Brand Defendants failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

199. Brand Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/MCP, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others, like Ms. Franzman.

200. Brand Defendants were also under a public duty to supply accurate and complete information regarding Reglan/MCP, including the risks and side effects, to users of Reglan/MCP, including Plaintiff, because users would ingest generic Reglan/MCP which contained a generic package insert with Brand Defendants' inadequate and misleading guidance and information.

201. Brand Defendants are liable to the Plaintiff under the *Restatement of Torts 2nd* § 552, Plaintiff and her prescribing physicians are the people intended to benefit from the Brand Defendants' public duty to supply accurate, non-misleading guidance and information and the people intended to be protected by such duty. In contrast to being protected, Plaintiff suffered losses as a result of Brand Defendants' failure to supply accurate, complete information and guidance in the PDR and their Reglan/MCP package insert, which was reprinted in the generics' package inserts, as required by law upon initial entry into the market, and also used by the PEM

Defendant.

202. Brand Defendants failed to review all adverse drug event information[14] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/MCP.

203. Brand Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/MCP for periods of time in excess of twelve weeks duration.

204. Brand Defendants were negligent and breached duties owed to the Plaintiff as a user and consumer with respect to the manufacture and sale of Reglan/MCP, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably design, manufacture, test, inspect, market, sell and/or distribute, Reglan/MCP so as to avoid the aforementioned risks to individuals;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects including death (particularly with foreseeable long-term use), despite Brand Defendants' knowledge of the defects and risks associated with Reglan/MCP ingestion;

c) Failing to reasonably and accurately represent to the prescribing physician(s) and ultimately thereby users and consumers, that the drug can cause central nervous system side effects and significant and permanent extra pyramidal symptoms, particularly with foreseeable long-term use;

d) Failing to conduct adequate pre-clinical and clinical testing (Wyeth) and conduct adequate and reasonable testing on the risks and side effects associated with long-term ingestion of Reglan/MCP (Brand Defendants) and conduct post marketing surveillance (Brand Defendants) to determine the safety of Reglan/MCP, and failing to monitor all relevant scientific literature related to Reglan/MCP;

[14] Defendants are required to review all adverse drug experience information obtained or otherwise received...from any source...including derived from postmarketing clinical investigations, postmarketing epidemiological/ surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R § 317.80(b).

e) Failing to adequately and reasonably inform the medical community that Reglan/MCP was unreasonably dangerous for long-term use, despite having knowledge, through their own studies and studies by independent investigators, that physicians frequently prescribed Reglan/MCP for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/MCP or through the Physician's Desk Reference (PDR) (Wyeth), the risks of Tardive Dyskinesia, Dystonia and other extrapyramidal side effects of Reglan/MCP, including, but not limited to the increased risks for patients who receive the drug for twelve weeks or longer;

f) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long-term ingestion of Reglan/MCP, once the side effects became actually or constructively known; with the knowledge that this information would be disseminated to physicians who would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

g) Failing to reasonably and properly conduct and report adequate postmarketing surveillance and testing to determine the safety of the product, particularly with foreseeable long-term use, despite Defendant Wyeth's knowledge of the defects and risks associated with Reglan/MCP ingestion;

h) Failing to reasonably and adequately warn that the long-term use of Reglan/MCP may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Stereotypy, Tremors, Visual Disturbances, etc., and that these side effects are permanent in nature;

i) Willfully and deliberately failing to adequately disclose all actually and/or constructively known risks regarding Reglan/MCP and in doing so, acting with a conscious disregard of Plaintiff's safety and/or welfare, and others similarly situated.

205. The negligence described above directly and proximately caused the Plaintiff's severe and permanent injuries, in that directly and in natural and continuous sequence produced and contributed substantially thereto, including, but not limited to the fact that Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors,

Stereotypy and Akathisia.

206. Brand Defendants made representations concerning Reglan/MCP in the course of their business as designers, manufacturers, and/or distributors of the drug.

207. The above misrepresentations were made to Plaintiff, her physicians, pharmacists, the medical community and the general public, all of whom justifiably and foreseeably relied on those representations or omissions.

208. Brand Defendants negligently disseminated misleading information to physicians and patient's across the country, including to Plaintiff, through but not limited to their drug representatives, drug advertisements and marketing, drug package inserts and/or their published version found in the PDR, about the risks of long-term ingestion of Reglan/MCP and/or of the increased risk or lack thereof of extrapyramidal side effects, including Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia.

209. Brand Defendants are liable for the negligent misrepresentations and omissions that were made negligently by them to Plaintiff, as well as, to Plaintiff's prescribing physicians to induce prescribing and purchase of their drug.

210. Brand Defendants are liable for their negligent conduct. Plaintiff came to rely upon the safety and soundness of the drug Reglan/MCP and so failed to appreciate or have knowledge of the risk associated with long-term ingestion of the drug.

211. Brand Defendants are liable for their negligent omission, concealment and failure to warn of the serious health risks, which caused Ms. Franzman to suffer injury, harm and economic loss as alleged herein, including permanent, substantial physical disability and/or interference with daily activities, as well as, physical pain and emotional distress.

212. Defendant Schwarz, as accepting and purchasing Defendant Wyeth's liability, is

also accordingly liable for the negligent misrepresentations and omissions that were made by Defendant Wyeth to Plaintiff, which caused her to suffer injury, harm and economic loss as alleged herein, including permanent, substantial physical disability and/or interference with daily activities, as well as physical pain and emotional distress.

213. Brand Defendants breached their duties and proximately caused, through their acts of negligence as described above, severe and permanent damage to the Plaintiff, Ms. Franzman.

214. As a direct and proximate result of the acts and omissions of the Brand Defendants, Plaintiff ingested Reglan/MCP as prescribed for periods in excess of twelve weeks duration and which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder.

COUNT II

NEGLIGENCE

PLAINTIFF V. WATSON (GENERIC DEFENDANT)

215. Plaintiff incorporates by reference all of the above paragraphs.

216. Generic Defendant specializes in the development, manufacture and sale of generic pharmaceuticals, including Reglan/MCP.

217. Generic Defendant, during all times material hereto, has regularly conducted business and supplied pharmaceutical medications, including but not limited to generic Reglan/MCP.

218. By way of information and belief Plaintiff ingested Reglan/MCP that was manufactured and sold by the Generic Defendant Watson during the time period in question.

219. Based upon information and belief Generic Defendant submitted Abbreviated

New Drug Applications (ANDA) to the FDA based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Reglan/MCP.

220. Under the ANDA process, the Code of Federal Regulations required Generic Manufacturers, including Generic Defendant Watson, to submit labels for generic Reglan/MCP initially identical in all material aspects to the reference listed drug label.

221. Under the Code of Federal Regulations, Generic Manufacturers, including Generic Defendant Watson, had a duty to ensure that Reglan/MCP warnings to the medical community are accurate and adequate, and to conduct post market safety surveillance, to review all adverse drug event information (ADE) and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/MCP.

222. Under the Code of Federal Regulations if a generic drug manufacturer, including the Generic Defendant Watson, discovers subsequent information in the course of the fulfillment of its duties as outlined above, the Generic Defendant is obligated to report that information to the medical community, and thereby Plaintiff's physicians, so that Plaintiff and other foreseeable users of Reglan/MCP are apprised of warnings and updates that are accurate and adequate.

223. Despite these requirements, Generic Defendant failed to investigate the accuracy of its generic bioequivalent Metoclopramide and/or Metoclopramide HCl drug label. As a direct result, Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors and Akathisia.

224. Based upon information and belief, Generic Defendant unreasonably failed to review the medical literature for its Reglan/MCP and instead relied upon the name brand manufacturer and the RLD to review the aforementioned medical literature and thus failed to

communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/MCP. As a result the Plaintiff came to rely upon the safety and soundness of said drug, and so failed to appreciate or have knowledge of the risk associated with long-term ingestion of the drug.

225. Generic Defendant was negligent and breached duties owed to the Plaintiff as a user and consumer with respect to the manufacture and sale of Reglan/MCP, as set forth otherwise herein and for reasons including, but not limited to the following:

a) Failing to reasonably design, manufacture, test, inspect, market, sell and/or distribute, Reglan/MCP so as to avoid the aforementioned risks to individuals;

b) Failing to reasonably accompany the drug with adequate warnings, instructions and updates regarding the adverse and permanent side effects including death (particularly with foreseeable long-term use), despite Generic Defendant's knowledge of the defects and risks associated with Reglan/MCP ingestion;

c) Failing to reasonably and accurately represent to the prescribing physician(s) and ultimately thereby users and consumers, that the drug can cause central nervous system side effects and significant and permanent extra pyramidal symptoms, particularly with foreseeable long-term use;

d) Failing to conduct adequate post marketing surveillance to determine the safety of Reglan/MCP, and failing to monitor all relevant scientific literature related to Reglan/MCP;

e) Failing to adequately and reasonably inform the medical community that Reglan/MCP was unreasonably dangerous for long-term use, despite having knowledge, through Generic Defendant's own studies and/or studies by independent investigators, that physicians frequently prescribed Reglan/MCP for long-term use;

f) Failing to reasonably and sufficiently disclose information in package inserts for Reglan/MCP or through the Physician's Desk Reference (PDR), of the risks of Tardive Dyskinesia, Dystonia, Tremors and other extra pyramidal side effects of Reglan/MCP, including, but not limited to the increased risks for patients who receive the drug for twelve weeks or longer;

g) Failing to reasonably and promptly correct and/or amend the package inserts, PDR monographs, and literature regarding the risks of long-term ingestion of Reglan/MCP, once the side effects became actually or constructively known; with the knowledge that this information would be disseminated to physicians who would rely upon that information in their decisions concerning the prescription of drug therapy for their patients;

h) Failing to reasonably and properly conduct and report adequate post marketing surveillance and testing to determine the safety of the product, particularly with foreseeable long-term use, despite Generic Defendant's knowledge of the defects and risks associated with Reglan/MCP ingestion;

i) Failing to reasonably and adequately warn that the long-term use of Reglan/MCP may result in side effects such as Depression with Suicidal Ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Tremors, Orolingual Facial Buccal Stereotypy, Visual Disturbances, etc., and that these side effects are permanent in nature; and/or

j) Willfully and deliberately failing to adequately disclose all actually and/or constructively known risks regarding Reglan/MCP and in doing so, acting with a conscious disregard of Plaintiff's safety and/or welfare, and others similarly situated.

226. The negligence described above directly and proximately caused Plaintiff severe and permanent injuries, in that it directly and in natural and continuous sequence produced and contributed substantially thereto, including but not limited to the fact that Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia.

227. Generic Defendant breached its duties, and proximately caused through a defective product and/or through its acts of negligence, severe and permanent damage to the Plaintiff, Ms. Franzman.

228. Generic Defendant is therefore liable for its intentional, reckless, and/or negligent omission, concealment and failure to warn of the design and manufacturing defects which caused Plaintiff to suffer injury, harm and economic loss, including medical bills, medical expenses, and

including permanent and substantial physical disability.

229. As a direct and proximate result of the acts and omissions of the Generic Defendant, Plaintiff ingested Reglan/MCP as prescribed and, unbeknownst to her, Plaintiff's ingestion of Reglan/MCP was causally related to and substantially contributed to her development of a permanent neurological disorder.

COUNT III

BREACH OF WARRANTY

PLAINTIFF V. WATSON (GENERIC DEFENDANT)

230. Plaintiff incorporates by reference all of the above paragraphs.

231. Through promotional statement(s) and product literature Generic Defendant, Watson, expressly warranted to the medical community and thereby ultimately the user and consumer, including Plaintiff, that Reglan/MCP was safe and capable of treating gastrointestinal disorders over an extended period of time (i.e. over twelve weeks), despite Generic Defendant's knowledge to the contrary.

232. The Generic Defendant knew or should have known that its warranties regarding safety for long-term use would be relied upon by the medical community which included ordinary, reasonable and prudent physicians who would share that information with others in the medical community and that eventually prescribing physicians and the public, including the Plaintiff, would come to rely and did rely upon Generic Defendant's express warranties about Reglan/MCP's safety for long-term use.

233. The Generic Defendant's express warranties about the safety of Reglan/MCP for long-term use were false and intentionally misleading.

234. Despite knowledge to the contrary, the Generic Defendant continued to promote,

sell and market the safety of Reglan/MCP, while having knowledge of the design, manufacturing, safety defects and risk that the drug posed to the user and consumer of developing severe neurological side effects such as Tardive Dyskinesia, Dystonia, Stereotypy, Tremors and Akathisia with prolonged use of the drug.

235. The Generic Defendant, through its marketing, promoting, selling and distribution of Reglan/MCP represented that the drug product was of merchantable quality and safe and fit for its intended use of treating gastrointestinal symptoms such as gastroesophageal reflux and gastroparesis. At the same time the Generic Defendant continued to conceal and continued to fail to warn of the risks and side effects of neurological disorders such as Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia which were associated with long-term use of Reglan/MCP, and continued to impliedly warrant the medical soundness of the drug to the medical community and thereby general public. As a direct result, Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia.

236. Ms. Franzman and her prescribing physicians reasonably relied on the presumption that the Generic Defendant would provide notice, disclosure or warnings of any serious risks associated with the merchantability, quality, safety and fitness for the intended use of Reglan/MCP.

237. Contrary to such implied warranties, Reglan/MCP was not of merchantable quality or safe or fit for its intended use, because the drug was and is unreasonably dangerous and unfit for the ordinary, intended and foreseeable use due to its adverse side effects and inadequate warnings of serious health risks.

238. As a direct and proximate result of the Generic Defendant's breach of warranty, Ms. Franzman ingested Reglan/MCP as prescribed, which unbeknownst to her was causally related to and substantially contributed to her development of a permanent neurological disorder.

239. Plaintiff has duly given notice to the Generic Defendant of the breach of the above-described warranties.

COUNT IV

MISREPRESENTATION AND FRAUD

PLAINTIFF V. WATSON (GENERIC DEFENDANT)

240. Plaintiff incorporates by reference all of the above paragraphs.

241. Generic Defendant, Watson, intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/MCP and the increased risk of extrapyramidal side effects, including Tardive Dyskinesia and Dystonia.

242. The Generic Defendant misrepresented the soundness and reliability of Reglan/MCP to physicians and the medical community, and thereby ultimately the general public through promotional and marketing campaigns. The Generic Defendant misrepresented that the drug was safe and effective when used as prescribed, when in fact, Reglan/MCP was dangerous to the health of patients, and continued these misrepresentations for an extended period of time, without disclosing material information that was available to Watson. As a direct result, Plaintiff's prescribing physicians prescribed Reglan/MCP in a manner that they would not have, had the physicians known of the significant risks of, inter alia, Tardive Dyskinesia, Dystonia, Tremors, Stereotypy and Akathisia.

243. The Generic Defendant concealed the design, manufacturing and safety defects

from the public by withholding information pertaining to the design, manufacturing, safety defects and risks of severe and permanent neurological side effects related to the ingestion and long-term use of Reglan/MCP, while knowingly presenting inaccurate safety and risk information to the medical community and thereby ultimately the general public, users and consumers, including the Plaintiff, Ms. Franzman.

244. The Generic Defendant knew of the risks that Reglan/MCP presented to users and consumers when consumers, like Ms. Franzman, unknowingly ingested the drug product as prescribed for periods exceeding twelve weeks in duration.

245. The Generic Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Reglan/MCP and otherwise failed to exercise reasonable care in transmitting information to the medical community and thereby ultimately to the general public, users and consumers, including the Plaintiff.

246. The Generic Defendant made these representations concerning Reglan/MCP in the course of its business a designer, manufacturer, and distributor of the drug.

247. Such representations were made by the Generic Defendant with the intent to defraud and/or deceive the medical community and thereby ultimately the users and consumers of Reglan/MCP and with the knowledge and intent to induce reliance upon these representations and use of said drug product.

248. As a direct and proximate result of the acts and omissions of the Generic Defendant, Plaintiff ingested Reglan/MCP as prescribed, and unbeknownst to her, the drug was causally related to and substantially contributed to her development of a permanent neurological disorder. Ms. Franzman would not have suffered her injuries but for the above fraud,

concealment, misrepresentations or omissions of the Generic Defendant.

249. In doing the acts alleged in this Petition, the Generic Defendant acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to the Generic Defendant's wealth, and sufficiently large to be an example to others and to deter the Generic Defendant, and others from engaging in similar conduct in the future.

COUNT V

NEGLIGENCE

PLAINTIFF V. FIRST DATABANK

(PEM DEFENDANT)

250. Plaintiff incorporates by reference all of the above paragraphs.

251. Upon information and belief, written Reglan/MCP drug package inserts, patient drug information forms, counseling, warnings, or literature, provided to Army Pharmacy's customers, including the Plaintiff, if any, by her Pharmacy, were created, written, edited, provided and made available to Plaintiff's Pharmacy, by PEM Defendant, FDB, pursuant to agreement, formal or informal, written or unwritten, between the Army Pharmacy and PEM Defendant, or otherwise, for purposes of providing same to Plaintiff's Pharmacy's customers, including the Plaintiff.

252. The Plaintiff received, read and relied upon FDB's PEM, including the risk and safety information, which was provided to her by Army Pharmacy with her Reglan/MCP prescription.

253. Upon information and belief, written Reglan/MCP drug database information, clinical decision support modules, drug monographs, drug package inserts, patient drug

information forms, counseling, warnings, or literature, provided to physicians, hospitals, pharmacists and pharmacies, including, upon information and belief, Plaintiff's pharmacists and physicians, were created, written, edited, provided and made available to them, by PEM Defendant, pursuant to agreement, formal or informal, written or unwritten, between physicians, hospitals, pharmacists and pharmacies and PEM Defendant, or otherwise, for purposes of providing them drug information to use and rely upon when prescribing, dispensing and counseling regarding Reglan, Metoclopramide and/or Metoclopramide HCl to and for their patients, including, upon information and belief, the Plaintiff.

254. The PEM Defendant undertook and had a duty to provide truthful, accurate, useful, appropriate and complete information and warnings in the written Reglan/MCP PEMs, patient drug information forms, counseling, warnings, or literature, that FDB created, wrote, edited, provided and made available to Plaintiff's Pharmacy to be distributed to its customers, including the Plaintiff.

255. The PEM Defendant undertook and had a duty to provide truthful, accurate, useful, appropriate and complete information and warnings in the written Reglan/MCP drug database information, clinical decision support modules, drug monographs, forms, counseling, warnings, or literature, that it created, wrote, edited, provided and made available to physicians, hospitals, pharmacists, and pharmacies, including, upon information and belief, Plaintiff's pharmacists and physicians.

256. The PEM Defendant undertook a duty under Section 324A of the *Restatement 2d*

of Torts[15] when it provided drug information services, including a PEM, to the Plaintiff's Pharmacy and, upon information and belief, Plaintiff's physicians, drug information which the PEM Defendant was aware was necessary for the protection of Plaintiff.

257. The PEM Defendant FDB failed to comply with its obligations set forth in common law, the Keystone Guidelines, unfair trade practices and consumer protection law and Section 324A of the *Restatement 2d of Torts*, when it failed to provide scientifically accurate, comprehensive, timely and up-to-date, useful information to Plaintiff regarding the risks associated with Reglan/MCP use, including, but not limited to, the 1 in 5 chance of developing an involuntary movement disorder with use of the drug in excess of twelve weeks.

258. The PEM Defendant deceptively, recklessly, improperly, and negligently failed to provide truthful, accurate, appropriate and complete information and warnings in the written Reglan/MCP PEMs, patient drug information forms, counseling, warnings, or literature, that it created, wrote, edited, provided and made available to the Plaintiff's Pharmacy to be distributed to the Pharmacy's customers, including the Plaintiff, also in violation of common law, unfair trade practices and consumer protection law, the Keystone Guidelines and Section 324A of the *Restatement 2d of Torts.*

259. The PEM Defendant recklessly, improperly, and negligently failed to provide truthful, accurate, appropriate and complete information and warnings in the written

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[15] *§ 324A.* Liability To Third Person For Negligent Performance Of Undertaking

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Reglan/MCP drug database information, clinical decision support modules, drug monographs, forms, counseling, warnings, or literature, that it created, wrote, edited, provided and made available to physicians, hospitals, pharmacists, and pharmacies, including, upon information and belief, Plaintiff's pharmacists and physicians. Pharmacists and physicians relied upon the inadequate information provided to them by PEM Defendant when prescribing, dispensing and counseling regarding Reglan/MCP.

260. The PEM Defendant is liable to Ms. Franzman under Section 324A of the *Restatement 2d of Torts*, for the injuries that resulted from its failure to use reasonable case in its undertaking to provide scientifically accurate, up-to-date drug information to the Plaintiff's Pharmacy, and, upon information and belief, Plaintiff's physicians, because: 1) the PEM Defendant's failure increased the risk of harm to Plaintiff; 2) Plaintiff suffered harm because of her reliance on the PEM Defendant's provision of inadequate Reglan/MCP drug information, specifically the patient education monograph, and other drug information provided, upon information and belief, to Plaintiff's physicians and conveyed to them; and/or 3) Plaintiff suffered harm because of Plaintiff's pharmacists and physicians reliance on the PEM Defendant's provision of inadequate Reglan/MCP drug information provided to them by PEM Defendant FDB when prescribing, dispensing and counseling regarding Reglan/MCP.

261. As a direct and proximate result of the acts and omissions of the PEM Defendant, Plaintiff ingested Reglan/MCP as prescribed and for periods in excess of 12 weeks duration, which unbeknownst to her and, upon information and belief, unbeknownst to her prescribing physicians and pharmacists, was causally related to and substantially contributed to her development of a permanent tremor and involuntary movements of her jaw, mouth, and eyes.

262. As a direct and proximate result of the acts and omissions of the PEM

Defendant's conduct, Plaintiff suffered injury, harm and economic loss, including medical bills, medical expenses, including permanent and substantial physical disability, physical pain, and emotional distress.

263. As a direct and proximate result of the acts and omissions of the PEM Defendant, Plaintiff suffered among other things extreme emotional distress, anguish, physical and mental suffering, weakness and involuntary shaking, tremors and continuous involuntary movements of her body rendering her physically and permanently injured.

264. As a direct and proximate result of the acts and omissions of the PEM Defendant, Plaintiff has experienced extreme embarrassment, shame, anguish, anxiety, and an inability to be involved in daily activities.

265. By virtue of its individual and collective acts and omissions, the PEM Defendant is jointly and severally liable, along with the other Brand and Generic Manufacturing Defendants, to Ms. Franzman as such acts and omissions have proximately caused her to suffer a single indivisible injury for which each of the Defendants is responsible.

266. Pursuant to Section 538.225 of the Missouri Revised Statutes, attached hereto as **Exhibit "A"** is a copy of the Affidavit of Plaintiff's Attorney Certifying the Merits of the Case as to First DataBank, which attests that there is reasonable cause for filing the instant action against the PEM Defendant and that Plaintiff's claims against the First DataBank are meritorious.

COUNT VI

STRICT PRODUCT LIABILITY

PLAINTIFF V. WATSON

(GENERIC DEFENDANT)

267. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Petition with the same force and effect as if fully set forth herein.

268. At all relevant times the Generic Defendant was engaged in the business of manufacturing, designing, marketing, promoting, distributing, and/or selling Reglan/MCP.

269. At all times mentioned in this Petition, Reglan/MCP was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the Generic Defendant.

270. Reglan/MCP was "defective" and "unreasonably dangerous" when the product initially was patented, and subsequently when it was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:

a) At the time Reglan/MCP left the control of the Generic Defendant it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the product breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.

b) Reglan/MCP was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the Generic Defendant, and that such risks clearly outweighed the utility of the product or its therapeutic benefits.

c) At the time Reglan/MCP left the control of the Generic Defendant it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the Generic Defendant. Specifically, although the Generic Defendant was well aware that Reglan/MCP could potentially cause central nervous system side effects, depression with suicidal ideation, Akathisia, Akinesia, Tardive Dyskinesia, Tardive Dystonia, Tremors, Stereotypy, visual disturbances and interference with the metabolism of other prescription drugs and in fact, had significantly greater prevalence and severity of these side effects in patients with diabetes mellitus, warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform reasonably prudent physicians and consumers. Generic Defendant failed

to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of Reglan/MCP.

d) Generic Defendant's warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the product, such as Plaintiff.

e) The Metoclopramide manufactured and supplied by the Generic Defendant was further defective due to inadequate post marketing warning or instruction because, after the Generic Defendant knew or should have known of the risks of injury from Reglan/MCP associated with long-term use as commonly prescribed, the Generic Defendant failed to promptly respond to and adequately warn about extrapyramidal side effects, among other adverse reactions.

271. Generic Defendant knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Ms. Franzman seeks recovery. A reasonably competent physician who prescribed Metoclopramide and a reasonably competent Plaintiff who consumed Metoclopramide would not have realized the drugs' dangerous condition.

272. Generic Defendant knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of Reglan/MCP that caused the damages for which Plaintiff seeks recovery.

273. The reasonably foreseeable use of Reglan/MCP, involved substantial dangers not readily recognizable by the ordinary physician who prescribed Reglan/MCP or the patient, like Plaintiff, who consumed Reglan/MCP.

274. Generic Defendant knew that the Reglan/MCP was to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that Reglan/MCP was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at

the time of distribution.

275. Plaintiff and her physicians did not know, nor had reason to know, at the time of the use of Reglan/MCP, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

276. These defects caused serious injuries to Ms. Franzman when she used the product in its intended and foreseeable manner, and in the manner recommended by the Generic Defendant or in a non-intended manner that was reasonably foreseeable.

COUNT VII

VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT

PLAINTIFF V. ALL DEFENDANTS

277. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

278. At all times relevant, the Missouri Merchandising Practices Act, VAMS §§ 407.010 et seq., (hereinafter "MPA") prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce" and declares such acts or practices as unlawful."

279. Defendants violated the MPA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Reglan/MCP. Defendants communicated the purported benefits of Reglan/MCP while failing to disclose the serious and dangerous side effects related to the use of Reglan/MCP with the intent that consumers, like Plaintiff, and her physicians would rely upon the

misrepresentations and purchase or prescribe Reglan/MCP.

280. As a result of violating the MPA, Defendants caused Ms. Franzman to be prescribed and to use Reglan/MCP, causing severe injuries and damages as previously described herein.

COUNT VIII

JOINT AND SEVERAL LIABILITY

PLAINTIFF V. ALL DEFENDANTS

281. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Petition with the same force and effect as if fully set forth herein.

282. By virtue of their individual and collective acts and omissions, Defendants are jointly and severally liable to Ms. Franzman, as such acts and omissions have proximately caused Plaintiff to suffer injuries for which each Defendant is responsible.

COUNT IX

PUNITIVE DAMAGES

PLAINTIFF V. ALL DEFENDANTS

283. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Petition with the same force and effect as if fully set forth herein.

284. The conduct of each Defendant, as set forth herein above was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that each Defendant acted only out of self interest and personal gain. Such conduct evidences a specific intent to cause harm to Ms. Franzman as provided under Missouri law. Accordingly, punitive damages should be imposed against each Defendant pursuant Missouri law, to punish and deter each Defendant

from repeating or continuing such unlawful conduct.

COUNT X

PLAINTIFF'S DAMAGES

PLAINTIFF V. ALL DEFENDANTS

285. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Petition with the same force and effect as if fully set forth herein.

286. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiff has:

a) suffered severe and permanent injuries, which she will be forced to endure for the remainder of her life;

b) suffered physical impairment and disfigurement;

c) suffered physical pain and suffering;

d) suffered mental pain and suffering;

e) had her enjoyment of life severely impaired;

f) incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating her injuries; and/or

g) incurred attorney's fees and expenses of litigation related to this action.

WHEREFORE, Plaintiff demands judgment against the Defendants and requests that this Honorable Court:

a) enter a judgment against each Defendant, jointly and severally, for all general and compensatory damages allowable to Plaintiff;

b) enter a judgment against each Defendant, jointly and severally, for all special damages allowable to Plaintiff;

c) enter a judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiff under this Petition;

d) order the costs of this action be cast upon Defendants; and

e) grant Plaintiff such further relief, which the Court deems just and appropriate.

PLAINTIFF CLAIMS A TRIAL BY JURY.

Date: February 10, 2011

Respectfully submitted,

PLAINTIFF,
By Her Attorneys,

SCHLICHTER, BOGARD & DENTON

By: _____
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Exhibit A

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

HELEN FRANZMAN,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 1022-CC12326
	)	
WYETH, INC., et al.,	)	
	)	
Defendants.	)	
	)	

AFFIDAVIT OF PLAINTIFF'S ATTORNEY CERTIFYING THE MERITS OF THE CASE AS TO DEFENDANT FIRST DATABANK PURSUANT TO R.S.MO. §538.225 REGARDING DR. J. DAVID HAYES

COMES NOW, Elizabeth Wilkins, counsel for Plaintiff, and, being duly sworn upon her oath, states and deposes as follows:

1. My name is Elizabeth Wilkins and I am counsel of record for Plaintiff Helen Franzman, in the above entitled action. The statements contained in this affidavit are made based on my own personal knowledge and on my review of the written opinion letter of Dr. J. David Hayes.

2. I have consulted with Dr. Hayes, whose address is 6902 Lawler Ridge, Houston, Texas 77055. Dr. Hayes is a pharmacist licensed to practice in Texas and, as a legally qualified healthcare provider, will certify the merits of the Plaintiff's cause of action for damages for personal injuries on account of the failure by Defendant First DataBank to render proper health care services. Dr. Hayes is a board certified pharmacotherapy specialist. In May 1997, Dr. Hayes graduated from the University of Houston, receiving his Doctor of Pharmacy. Since then, Dr. Hayes has held academic appointments as an Instructor at the Baylor College of Medicine and University of Texas at Austin College of Pharmacy. Currently, Dr. Hayes serves as a

Clinical Associate Professor of Pharmacy at the University of Houston. Dr. Hayes has authored over twenty (20) publications and abstracts in the fields of pharmacy and pharmacotherapy, as well as made over one hundred (100) presentations on particular topics of interest. Attached herewith as **"Exhibit B"** is a copy of Dr. Hayes' curriculum vitae.

3. Dr. Hayes has provided me with an opinion letter regarding the care and treatment rendered by Defendant First DataBank in relation to Ms. Franzman. In the letter, Dr. Hayes expresses the opinion that Defendant First DataBank failed to use such care as a reasonably prudent and careful health care provider would have used under similar circumstances.

4. Dr. Hayes further states that the failure by Defendant to use such reasonable care directly caused or directly contributed to cause the damages claimed in the Petition filed in this action.

5. This affidavit is made for the purposes of satisfying the requirements of §538.225 R.S.Mo.

ELIZABETH WILKINS #61284

Subscribed and sworn to before me on this 10th day of February, 2011.

ELIZABETH M. CARROLL
Notary Public - Notary Seal
State of Missouri
Commissioned for St. Louis County
My Commission Expires: November 04, 2012
Commission Number: 08508101

Elizabeth M. Carroll
NOTARY PUBLIC

My commission expires: 11/4/2012.